

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Form Approved: OMB No. Expiration Date: See OMB Statement Food and Drug Administration Washington, DC 20204

Y2K Assessment Survey Center for Food Safety and Applied Nutrition

	Name of Company:
	Address of Company:
N	nme of Y2K Coordinator (or contact):
	Title:
	PhoneNumber:
	E-Mail Address:
1.	Does your company have a plan for addressing the Y2K problem? Yes No
a.	Have you taken all necessary steps to assure that the information technology and automated systems (e.g., manufacturing, quality control, distribution systems) used in the facilities responsible for producing all of your FDA-regulated products are Y2K compliant?* (Please update us when any significant change in your status occurs.) Yes No (What date do you anticipate completing this task?)
2.	Has your assessment of your processing systems indicated any non-compliant operations that would jeopardize the food product safety? Yes No

^{*} Compliant means that the automated systems can accurately process date/time data (including, but not limited to, calculation, comparing, and sequencing) from, into, and between the twentieth and twenty4irst centuries, and the years 1999 and 2000 and leap year calculations. This includes identifying all of the systems and correcting and validating any solutions to the problems related to Y2K or implementing workarounds to deal with the problems. In addition, you should have written documentation (e.g., assessments, test results, reports from independent reviewers) to demonstrate that all possible steps have been taken to make the systems compliant or have written documentation of your workarounds.

3.	Do you have foreign suppliers of materials (e.g., raw materials, equipment) used in the manufacture and/or distribution of your products? Yes No			
	a.	(If Yes) Have you asked these foreign suppliers of their Y2K readiness? ☐ Yes ☐ No (When will this task be completed?)		
		140 (When will this task be completed:		
4.	in	you have contingency plans (i.e., a plan to deal with potential problems such as problems obtaining raw materials or in manufacturing, packaging, labeling, or distributing the ished product)? Yes		
		No (When do you expect to have one in place?) (Skip to Question 4b.)		
	a.	Where appropriate, have the components of the contingency plans been tested? Yes		
		☐ No (When do you expect to complete testing?)		
	b.	Do the contingency plans address potential problems with your key business partners (suppliers, vendors, distributors, and others)? Yes No		
	c.	Do your contingency plans address potential problems with foreign suppliers (e.g., establish establishment of alternate suppliers of materials)? Yes No		
5.		you have plans to increase production of your products due' to an anticipated increase in assumer demand due to Y2K concerns? Yes No		
	a.	If you face an increase in demand due to Y2K concerns on the part of consumers or actual production or supply problems, is an increase in production feasible at this time (i.e., as of the fourth quarter of 1999)? Yes No		

6.	Do you have an Internet site that provides information on the Y2K readiness of your			
	company?			
	☐ Yes (URL:)		
	□ No			
7.	Do you have a telephone number or other means to handle inquires from you	our customers on		
	your Y2K status?			
	☐ Yes (Telephone Number:)		
	□ No	/		
	1 10			
	President/CEO	Date		
	I ICSIGCII/CEO	Date		
	Thank you for your time in completing this survey.			
	The state of the s			
	Telephone interview conducted by:			
	FDA Y2K Survey			
	1101 Olivette Executive Pkwy., Suite 200			

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing this burden to:

St. Louis, MO 63132

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An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.